K110071

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

JAN 3 1 2011

Device Name
Proprietary Device Name: COR Analyzer

Establishment Name and Registration Number of Submitter

Name: RCADIA Medical Imaging Ltd. (RCADIA hereafter)
Registration: 3006850219
Submission contact: Dan Laor
Sireni 6, Haifa 32972, Israel
TEL: 972-4-8246632

Device Classification

Product Code:	LLZ
Regulation Number:	892.2050
Common Name:	PACS - Picture archiving &communications system
Classification Name:	Picture archiving and communications system
Regulatory class:	Class II

Reason for 510(k) Submission
Modification of legally marketed device - Special 510(K)

Identification of Legally Marketed Predicate (un modified) Device
K072242 COR Analyzer II Manufacturer : RCADIA

Description of the Device Modifications
The COR Analyzer (unmodified) device is a post processing software application which runs on a stand-alone server, work-station. The device input is Computed Tomography Angiography (CTA) set of images. The Device Software provides the location and segmentation of the (RCA, LM, LAD & LCX) coronary arteries. The software also labels these arteries and displays them uniquely colored in a 3D view. Artery changes of volumes are processed and deviations from expected values are detected. When a deviation exceeds threshold value it is displayed on the 3D view. The device has been modified to include also the location, segmentation & processing of major branches (of the RCA, LM, LAD & LCX) arteries. The device reliability & user interface have been modified to improve convenience of use.

Indications for use
The COR Analyzer is intended to assist a trained physician to analyze Computed Tomography (CT) Angiographic images. The device is not intended for use with mammography. The COR Analyzer is specifically indicated to provide visualization of the major coronary vessels and lesions, thus assisting the physician in visualizing the coronary anatomy and pathology. COR Analyzer has abilities for coronary vessels segmentations, abnormalities display and processing

Safety & Effectiveness
The device has been designed, verified and validated complying with 21CFR 820.30 regulations. The device has been designed to meet the requirements of ISO 14971 Safety standard. Its performance has been validated by comparison the processing results to experienced radiologists' interpretation of the same data and to the processing results of the predicate device. The comparison results demonstrate that the COR Analyzer meets the required specifications and indications for use. No adverse affects have been detected.

Substantial Equivalency
It is Rcadia Medical Imaging Ltd. opinion that the COR Analyzer is substantially equivalent in terms of indications for use, safety and effectiveness to the unmodified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Dan Laor
Quality & Regulatory affairs Advisor
Rcadia Medical Imaging Ltd.
6 Sireni
Haifa 32972
ISRAEL

JAN 3 1 2011

Re: K110071
Trade/Device Name: COR Analyzer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 5, 2011
Received: January 10, 2011

Dear Mr. Laor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110071

Device Name: COR Analyzer

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Prescription Use **X** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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